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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,330

06/26/2003

Armand Malnoe

115808-365

4205

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BELL, BOYD & LLOYD LLP  
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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

02/05/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

**Office Action Summary**

Application No.

10/607,330

Applicant(s)

MALNOE ET AL.

Examiner

Deborah A. Davis

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6,8,10,11,14,16,18,63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) 23-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8,10,11,14,16,18,63 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group A, the phytochemical Sesquiterpene lactones, and Group B, the plant material chicory in the reply filed on October 29, 2007 is acknowledged. Currently claims 1, 3-4, 6, 8, 10-11, 14, 16, 18, 63 and 64 are under consideration. All other claims are cancelled or withdrawn from consideration.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ernest et al (US 6,200,594).

A composition comprising a therapeutically effective amount of a thermally processed plant material that includes one or more phytochemical agents from the group consisting of sesquiterpene lactones and further comprises a component selected from the group consisting of a starch source, a protein source or a fat source and combinations thereof is apparently claimed.

The reference of Ernest et al beneficially teaches the claims by teaching a composition of plant material that includes the sesquiterpene lactones (i.e. phytochemical) extracted from Blessed thistle. The compositions include suitable emollients (fat source) such as silicone oils, and cocoa butter. The plant materials are thermally processed by a method of steeping or boiling in an organic solvent. Ernest discloses that Blessed thistle has evidence of anti-inflammatory properties (see abstract, column 5, lines 48-64, column 6, lines 49-58, column 7, lines 50-55, e.g.).

The reference of Ernest et al does not teach expressly that the plant materials are from 0.5% to less than 5% of the composition.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify conventional working conditions such as percentages because it is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

Claims 1, 3, 8, 10, 11, 16, 18, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang et al (US 5,905,089).

A composition comprising a therapeutically effective amount of a thermally processed plant material that includes one or more phytochemical agents from the group consisting of sesquiterpene lactones with an active fragment that includes  $\alpha$ -methylene- $\gamma$ -butyrolactone wherein the plant material comprises an amount from at least 0.5% to less than 5%, and further comprises a component selected from the group consisting of a starch source, a protein source or a fat source and combinations thereof.

The reference of Hwang et al beneficially teaches sesquiterpene lactone containing plant extracts (composition) which has an  $\alpha$ -methylene- $\gamma$ -lactone functional group that is capable of inhibiting or reducing the severity of a severe inflammatory response from enzyme activity, therefore it would appear that the referenced composition would be capable of inhibiting enzymatic activity derived from cyclooxygenase and transcriptional activity derived from NF-kB. The composition further includes a fat source such as olive oil, as claimed. Such active sesquiterpene lactones may be used in various combination or mixtures (see abstract, column 5, lines 1-5, lines 40-65, column 6, lines 14-36, Example 1, e.g.).

The reference of Hwang et al does not teach the particular percent ranges of the composition, a particular  $\alpha$ -methylene- $\gamma$ -butyrolactone and is silent with respect to the plant material being thermally processed.

It would have been obvious to one of ordinary skill in the art to modify conventional working conditions as percent ranges as needed because it is deemed to be merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan. It would have been further obvious to substitute one

known  $\alpha$ -methylene- $\gamma$ -lactone functional group for another and achieve a predictable result of reducing enzyme activity. Although Hwang is silent with respect to the plant material being thermally processed, thermally processed plant material is well known and conventionally practiced in the art.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

Claims 4, 6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ernest et al and Hwang (US 5,905,089) as applied to claims 1, 3, 8, 10, 11, 16, 18, 63 and 64, and further in view of Olivier Hermand (US 6,645,534).

The teaching of Ernest et al and Hwang et al are set forth, but does not disclose that the plant material comprises a chicory extract.

The reference of Hermand beneficially teaches a chicory extract with a concentration of 4.5% by weight that has anti-inflammatory and anti-microbial properties. In the case of roasted chicory extract, the temperature does not exceed 170 degrees C. (column 2, lines, lines 9-42 and column 6, lines 14-24, e.g.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further include or substitute chicory taught by Hermand as a plant material in the composition taught by Ernest et al and Hwang et al based on its

beneficial teachings of having anti-inflammatory properties. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

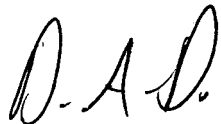
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Deborah A. Davis  
Patent Examiner  
Art Unit 1655  
January 2008



CHRISTOPHER R. TATE  
PRIMARY EXAMINER